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Canadian Patent

Brevet canadien

1315165

To all to whom these presents shall come:

Whereas a petition has been presented to the Commissioner of Patents praying for the grant of a patent for a new and useful invention, the title and description of which are contained in the specification of which a copy is hereunto attached and made an essential part hereof, and the requirements of the Patent Act having been complied with.

Now therefore the present patent grants to the applicant whose title thereto appears from the records of the Patent Office and as indicated in the said copy of the specification attached hereto, and to the legal representatives of said applicant for a period of seventeen years from the date of these presents the exclusive right, privilege and liberty of making, constructing, using and vending to the others in Canada the invention, subject to adjudication in respect thereof before any court of competent jurisdiction.

Provided that the grant hereby made is subject to the conditions contained in the Act aforesaid.

All patents are subject to annual maintenance fees subsequent to the modified Patent Act.

In testimony whereof, these letters patent bear the signature of the Commissioner and the seal of the Patent Office hereunto affixed at Hull, Canada.

This Patent was issued on:

A tous ceux qui les présentes verront:

Considérant qu'une requête a été présentée au Commissaire des brevets, demandant la délivrance d'un brevet pour une invention nouvelle et utile, dont le titre et la description apparaissent dans le mémoire descriptif et dont copie est annexée aux présentes et en fait partie essentielle, et que ladite requête satisfait aux exigences de la Loi sur les brevets.

A ces causes, le présent brevet confère au demandeur dont le titre de propriété dudit brevet est établi d'après les dossiers du Bureau des brevets et est indiqué dans ladite copie du mémoire descriptif ci-annexée, et aux représentants légaux dudit demandeur, pour une période de dix-sept ans, à compter de la date des présentes, le droit, la faculté et le privilège exclusifs de fabriquer, construire, exploiter et vendre à d'autres, au Canada l'invention, sauf jugement en l'espèce par un tribunal de juridiction compétente.

La concession faite par les présentes étant soumise aux conditions contenues dans la loi précitée.

Des frais annuels de maintien seront applicables pour tout brevet octroyé subséquement à la Loi modifiant la Loi sur les brevets.

En foi de quoi, ces lettres patentes portent la signature du Commissaire ainsi que le sceau du Bureau des brevets apposé à Hull, Canada.

Ce Brevet à été delivré le:

Date MAR 3 0 1993

Commissioner of Patents - Commissaire des brevets

Canada

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Consumer and Corporate Affairs Canada

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(54) Medical Device

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This invention relates to a medical device employing a needle having a guard member which permanently locks in place to protect against accidental needle sticks after the needle has been used. More particularly, it relates to an improved locking element to hold the guard securely in the locked position.

In our Canadian Patent Application Serial No. 563,168, filed March 31, 1988 and entitled MEDICAL DEVICE, there are described medical devices using needles having movable guard members which are locked permanently in position after the needle is used. The locking member is mounted on the needle shaft, and it is bonded to the shaft by an adhesive. The locking device includes a recessed portion which serves to capture a wedge-type collar piece integral with one end of the guard member. With the collar piece wedged in the recessed portion, the guard is locked in a permanent position once it has been moved forward to cover the tip of the needle.

The purpose of the guard member is to prevent accidental needle sticks. If, however, the bond between the locking element and the exterior surface of the needle fails, the guard member would move and possibly expose the tip of the needle. Moreover, in mass production of such medical devices, it is both expensive and inconvenient to secure the locking element to the needle by means of an adhesive. Although the medical devices described in the

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above-identified applications represent a substantial improvement in disposable needles, it is desirable to improve their design so that there would not be an accidental failure of the bond between the locking element and the shaft of the needle, and would also enable the devices to be mass-produced rapidly and inexpensively.

SUMMARY OF THE INVENTION

The present invention provides an improved medical device of the type described in the above-identified applications employing a novel locking element which is securely mounted around the shaft of the needle and facilitates mass production of these devices.

According to the present invention, there is disclosed a disposable needle assembly comprising an elongated needle element terminating in an open pointed tip adapted to penetrate the body of a patient, a guard member mounted around the shaft of the needle element and manually movable axially along the needle element between a first position where the guard member is displaced inwardly from the open pointed tip to expose the open pointed tip to enable it to penetrate the body of the patient and a second position where the guard member covers the open pointed tip to prevent needle sticks, and locking means mounted along the needle element for locking the guard member in the second position upon movement of the guard member from the first position to the second position, the locking means having integral therewith and extending therefrom an elongated stem member wherethrough a portion of the needle element extends.

The locking means and the stem member typically cover substantially over 50% of the surface of the exterior of the needle element.

The guard member preferably comprises a tubular member having a collar member at the rearward end thereof and a restricted opening at the forward end thereof towards the

open pointed tip, the open pointed tip extending through the restricted opening in the forward end when the guard member is in the first position.

In the preferred embodiment of the present invention, the stem member comprises a hub member at one end thereof, remote from the locking means, said hub member removably connecting said needle assembly to a syringe.

The hub member advantageously has a guard holding section extending therefrom towards the open pointed tip to securely hold the guard member in position when the guard member is in the first position.

Typically, the collar member of the guard member comprises two lateral tear drop slits, substantially opposed to each other and dividing the collar member into two generally semicircular elements.

The guard holding section preferably comprises a planar member which securely fits into the lateral slits of the guard member when the guard member is in the first position.

The locking means advantageously has a receptacle in which the collar member of the guard member snaps into upon movement of the guard member into the second position.

Furthermore, it is preferable that the collar member of the guard member has an expandable orifice. The locking means may include a ramp section forward of the receptacle which fits into and forces expansion of the orifice as the guard member approaches the receptacle to move into the second position, the receptacle having an elevated wall which acts as a stop for the collar member of the guard member to prevent axial movement of the guard member after the collar member snaps into the receptacle.

Typically, the needle assembly of the present invention comprises a sheath member which fits over the first pointed tip of the needle element when the guard member is in the first position to prevent exposure of the first pointed tip, the sheath member having one end closed

and an open end opposed to the closed end, the hub member fitting snugly into the open end of the sheath end, so that the sheath member encases the needle element and the guard member but may be manually removed by pulling it off the hub member, the sheath member comprising interior splines which coact with the hub member to facilitate connecting the needle assembly to the syringe and disconnecting the needle assembly from the syringe.

The stem member is preferably securely bonded to the shaft of the needle element. The locking means is typically made of a polymeric material molded and pressure-bonded about the needle element without the use of adhesives. This polymeric material is preferably a polypropylene which is resistant to gamma radiation used to sterilize the needle. Such a polymeric material is sold by the Himont Corporation of Wilmington, Delaware under the trade name Himont PD626.

Typically the guard member comprises a plurality of ribs molded in the exterior surface thereof, to facilitate grasping the guard member.

According to the invention in a second aspect, there is disclosed a syringe comprising a needle having a guard member adapted to cover the open pointed tip of the needle and to lock permanently in the position where the guard member covers the open pointed tip, a locking member mounted on the shaft of the needle for securing the guard member in the locking position, said locking member comprising an elongated stem member which is pressure-bonded to the needle shaft without the use of adhesives during the molding of the locking member around the needle shaft, said stem member covering a substantial portion of the surface of the exterior of the needle.

According to the invention in a third aspect, there is disclosed a medical device, comprising a needle having first and second ends, said first end designed to penetrate the body of a patient, said needle adapted to be placed in

communication with the end of a syringe by way of said second end, said guard axially movable between a first position in which the first end of said needle is exposed, and a second position in which said first end is shielded, a locking member disposed intermediate said first and second ends and distally of the end of said syringe for retaining said guard in said second position and an elongated stem member integral with the locking member and extending therefrom.

The present invention also discloses a method of manufacturing a disposable needle assembly including a guard member mounted around the shaft of a needle element and locking means for permanently securing the guard member in a position where the guard member covers the pointed tip of the needle element in order to prevent needle sticks, said method comprising the steps of securely holding in position a substantial portion of the shaft of the needle element by means of pins within a mold cavity having a configuration corresponding to the locking element, injecting molten polymer into the mold cavity under high pressure and letting the molten polymer cool and shrink around the needle shaft so as to firmly bond the locking element to the needle shaft.

The preferred embodiment of this invention illustrating all of its features will now be discussed in detail. This embodiment shows the improved device of this invention in the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The improved medical device of this invention is illustrated in the drawings, with like numerals indicating like parts, and in which:

Fig. 1 is a perspective view of the improved medical device of this invention contained in a two-piece, plastic translucent housing.

Fig. 2 is an exploded perspective view of the improved medical device of this invention.

Fig. 3 is a side elevational view, with sections broken away, showing the novel locking element molded in place on the needle and carrying the guard for the needle.

Fig. 4 is a cross-sectional view taken along line 4-4 of Fig. 1.

Fig. 5 is a cross-sectional view taken along line 5-5 of Fig. 4.

Fig. 6 is a cross-sectional view taken along line 6-6 of Fig. 5.

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 6.

Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 6.

Fig. 9 is a fragmentary view in cross section showing the guard member being moved into locking position.

Fig. 10 is a cross-sectional view taken along line 10-10 of Fig. 9.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As best illustrated in Figs. 1 through 4, the improved medical device 10 of this invention is contained within a housing 12 including a sheath 14 which has a closed end 16, an open end 18 and a cover 20 which fits over the open end of the sheath. The sheath 14 is an elongated member having a generally cylindrical configuration with a side wall 22 that tapers outwardly from the closed end 16 to the open end 18. Running lengthwise along the exterior

of the wall 22 are spaced apart splines 24 which facilitate grasping the sheath 14 and turning it. As will be explained hereafter, internal splines 25 facilitate attaching the device 10 to a syringe (not shown). Near the open end 18 of the sheath 14, the side wall 22 flares outwardly and then is formed into an annulus 26 extending upwardly from a ledge 28. The ledge 28 serves as a stop for the cover 20 which fits snugly over the annulus 26. The cover 20 is short relative to the sheath 14 and it has at one end a closed off 30 section surrounded by a series radial ribs 32 which terminate at their internal ends in a wall 34 which defines an open end 36 having an internal offset bore 38 (Figs. 4-6). The bore 38 mates with the annulus 26 of the sheath 14 when the cover 20 is placed over the sheath.

Within the housing 12 is contained the improved medical device 10, which is sterilized in housing 12 by gamma radiation. The device 10 includes an elongated needle element 40 having a truncated tip 42 at one end and a locking member 44 securely mounted to the other end 46 of the shaft. The locking element 44 carries a guard member 48 which is movable axially along the shaft of the needle element.

In accordance with one feature of this invention, the locking element 44 is a unitary structure including a locking section 50, a stem 52, and a hub 54. This locking element 44 is made of any suitable polymeric material and is formed using insert molding techniques where the needle element 40 is held securely in position within a mold cavity having a configuration corresponding to the configuration of the locking element 44. Molten polymer is injected into the mold cavity and a pair of pins (not shown) extend into the cavity and grasp the shaft of the needle element 40 to hold

the needle element 40 in position and prevent bowing or lateral movement during formation of the locking element 4'. It is highly desirable to hold the needle element 40 with pins because the improved medical device of this invention employs a needle element which is substantially longer than conventional devices. For example, it is two or three times the length of conventional needles used with syringes. This is so because the needle element 40 carries the locking element 44 and the guard member 48 which is movable axially along the shaft between a position where this needle is exposed as shown in Fig. 4 to a locking position where the guard member is moved forward as shown in Fig. 9 to cover the tip 42 of the needle element. After the molten polymeric material is injected into the cavity it cools and shrinks to firmly bond the locking element 44 to the needle shaft. Because a substantial portion of the exterior surface of the needle shaft is in intimate contact with the locking element 44, a secure bond is formed which is highly unlikely to rupture. Thus, the locking element 44 and needle shaft are safely attached to one another so that bond rupture is virtually eliminated. Moreover, the use of costly adhesives in securing the locking element 44 to the needle shaft is eliminated.

The locking element 44 includes a locking section 50 similar to that described in above-identified patent applications and includes a pair of shoulders 56 and 58 separated by an annular recess 60 which captures collar elements 62 and 64 of the guard member 48 when the guard member is moved to the forward position covering the tip 42 of the needle element 40. The stem 52 is essentially an elongated hollow cylindrical member extending between the locking section 50 and the hub 54. The open spaces A and B

in the body of the stem result from the pins (not shown) extending into the mold cavity and grasping the needle shaft. The hub 54 includes a connector piece 66 having an internal cavity 68 formed by an inwardly tapering wall 70 which terminates in a generally flat bottom 72. The end 46 of the needle shaft terminates at the bottom 72. At the mouth of the cavity 68 are a pair of dog ears 74 opposed to one another which enable device 10 to be removably attached to a syringe (not shown). An annular platform 76 extends around the base of the hub 54 and it has a block 78 lying lengthwise across its diameter. A planar member 80 having generally flat opposing faces 80a and 80b extends outwardly from the exposed side of the block 78. A rib 82 extends around the stem 52 between the faces 80a and 80b of the planar member. This rib 82 is used to hold the guard member 48 in the rearward position where tip 42 of the needle element 40 is exposed. This will be explained in greater detail hereinafter. Between the dog ears 74 and the annular platform 76 is an annular stopper 84 which closes off the open end 18 of the sheath 14 when the device 10 is placed inside the housing 12.

As best illustrated in Figs. 3, 4, 5 and 6, the guard member 48 is a generally cylindrical member having one end 86 open to allow the guard member to move over the tip 42 of the needle element 40 and at its other end are the collar elements 62 and 64 which coact with the locking section 50 of the locking element 44 to permanently lock the guard member in position when it is moved forward. Internal rails 87 guide the guard member 48 as it moves forward. The collar elements 62 and 64 are formed in the upper end of the guard member 48 by a pair of teardrop shaped slits 88 which oppose one another and run laterally along the side wall of

the guard member. The collar elements 62 and 64 form therebetween an open section, and each collar element includes a finger section 90 which wedges in to the annular recess 60 of the locking section 50. The teardrop slits 88 enable collar elements 62 and 64 to expand outwardly as the guard member 48 is moved forward. When the finger sections 90 are opposite the recess 60 they snap inwardly, moving from a flexed to a unflexed position allowing the finger sections to grasp and permanently lock guard member to the locking section 50.

OPERATION

To use the improved medical device 10 of this invention it is first removed from the housing 12 by detaching the cover 20 and then, while grasping the sheath 14, securing the device to a syringe (not shown). This is accomplished by grasping the sheath 14 and turning it so that the internal splines 25 engage the planar member 80 and cause the device 10 to rotate as the dog ears 74 are inserted into the syringe. The dog ears 74 will then grasp the locking elements on the syringe to secure the device 10 in position, whereupon, the sheath 14 is pulled off the device to expose the tip 42 of the needle element 40. A drug is added to the needle/syringe combination at this point. The user then inserts the needle element 40 into the patient, makes the injection, and then grasps the guard member 48, while withdrawing the needle element from the body of the patient. This moves the guard member 48 relative to the needle shaft so that the collar elements 62 and 64 slide over the locking section 50 and into the recess 60, permanently locking the guard member 48 in position to cover the tip 42 of the needle element 40.

The device 10 may now be discarded.

Because of the construction of the locking element 44, the device of this invention is easy to mass produce and additionally provides extra safety so that the guard member 48 in the forward position will never move accidentally due to a failure of the bond between the locking element and the shaft of the needle element 44.

SCOPE OF THE INVENTION

The above description presents the best mode contemplated in carrying out the invention. This invention is, however, susceptible to modifications and alternate constructions from the embodiment shown in the drawing and described above. Consequently, it is not the intention to limit this invention to the particular embodiment disclosed. On the contrary, the intention is to cover all modifications and alternate constructions coming within the spirit and scope of the invention as generally expressed by the following claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A disposable needle assembly comprising:

an elongated needle element terminating in an open pointed tip adapted to penetrate the body of a patient;

a guard member mounted around the shaft of the needle element and manually movable axially along the needle element between a first position where the guard member is displaced inwardly from the open pointed tip to expose the open pointed tip to enable it to penetrate the body of the patient and a second position where the guard member covers the open pointed tip to prevent needle sticks, and

locking means mounted along the needle element for permanently locking the guard member in the second position upon movement of the guard member from the first position to the second position, the locking means having integral therewith and extending therefrom an elongated stem member wherethrough a portion of the needle element extends.

2. The needle assembly as set forth in Claim 1, wherein the locking means and the stem member cover substantially over 50% of the surface of the exterior of the needle element.

3. The needle assembly as set forth in Claim 1, wherein the guard member comprises a tubular member having a collar member at the rearward end thereof and a restricted opening at the forward end thereof towards the open pointed tip, the open pointed tip extending through the restricted opening in the forward end when the guard member is in the first position.

4. The needle assembly as set forth in Claim 1, wherein the stem member comprises a hub member at one end thereof, remote from the locking means, said hub member removably connecting said needle assembly to a syringe.

5. The needle assembly as set forth in Claim 4, wherein said hub member has a guard holding section extending therefrom towards the open pointed tip to securely hold the guard member in position when the guard member is in the first position.

6. The needle assembly as set forth in Claim 3, wherein the collar member of the guard member comprises two lateral tear drop slits, substantially opposed to each other and dividing the collar member into two generally semicircular elements.

7. The needle assembly as set forth in Claim 6, wherein the guard holding section comprises a planar member which securely fits into the lateral slits of the guard member when the guard member is in the first position.

8. The needle assembly as set forth in Claim 3, wherein the locking means has a receptacle in which the collar member of the guard member snaps into upon movement of the guard member into the second position.

9. The needle assembly as set forth in Claim 8, wherein the collar member of the guard member has an expandable orifice and wherein the locking means includes a ramp section forward of the receptacle which fits into and forces expansion of the orifice as the guard member approaches the receptacle to move into the second position, the receptacle having an elevated wall which acts as a stop for the collar member of the guard member to prevent

axial movement of the guard member after the collar member snaps into the receptacle.

10. The needle assembly as set forth in Claim 4, further comprising a sheath member which fits over the first pointed tip of the needle element when the guard member is in the first position to prevent exposure of the first pointed tip, the sheath member having one end closed and an open end opposed to the closed end, the hub member fitting snugly into the open end of the sheath end, so that the sheath member encases the needle element and the guard member but may be manually removed by pulling it off the hub member, the sheath member comprising interior splines which coact with the hub member to facilitate connecting the needle assembly to the syringe and disconnecting the needle assembly from the syringe.

11. The needle assembly as set forth in Claim 1, wherein said stem member is securely bonded to the shaft of the needle element.

12. The needle assembly as set forth in Claim 1, wherein the locking means is made of a polymeric material molded and pressure-bonded about the needle element without the use of adhesives.

13. The needle assembly as set forth in Claim 1, wherein the guard member comprises a plurality of ribs molded in the exterior surface thereof, to facilitate grasping the guard member.

14. A syringe comprising:

a needle having a guard member adapted to cover the open pointed tip of the needle and to lock permanently in the position where the guard member covers the open pointed tip;

a locking member mounted on the shaft of the needle for securing the guard member in the locking position,

said locking member comprising an elongated stem member which is pressure-bonded to the needle shaft without the use of adhesives during the molding of the locking member around the needle shaft, said stem member covering a portion of the needle.

15. A medical device, comprising:

a needle having first and second ends, said first end designed to penetrate the body of a patient, said needle adapted to be placed in communication with the end of a syringe by way of said second end;

a guard axially movable between a first position in which the first end of said needle is exposed, and a second position in which said first end is shielded;

a locking member disposed intermediate said first and second ends and distally of the end of said syringe for retaining said guard in said second position; and

an elongated stem member integral with the locking member and extending therefrom.

16. A method of manufacturing a disposable needle assembly including a guard member mounted around the shaft of a needle element and locking means for permanently securing the guard member in a position where the guard member covers the pointed tip of the needle element in order to prevent needle sticks, said method comprising the steps of:

securely holding in position a substantial portion of the shaft of the needle element by means of pins within a mold cavity having a configuration corresponding to the locking element;

injecting molten polymer into the mold cavity under high pressure;

letting the molten polymer cool and shrink around the needle shaft so as to firmly bond the locking element to the needle shaft.

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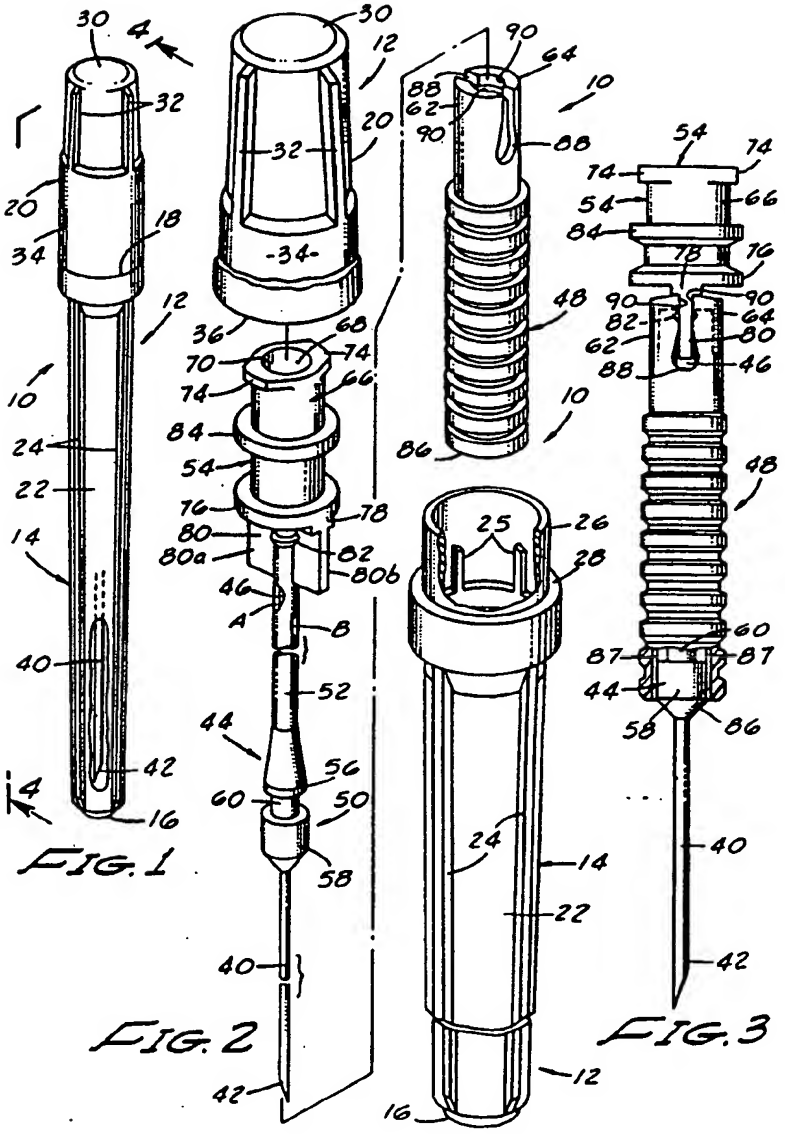

FIG. 1

FIG. 2

FIG. 3

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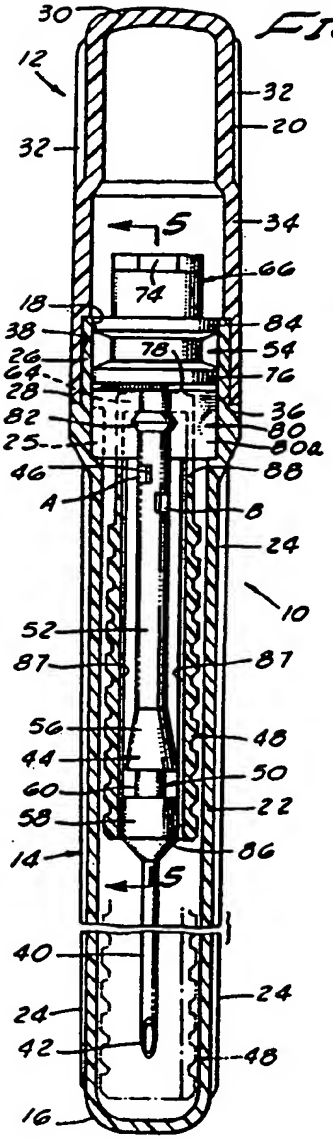

FIG. 4

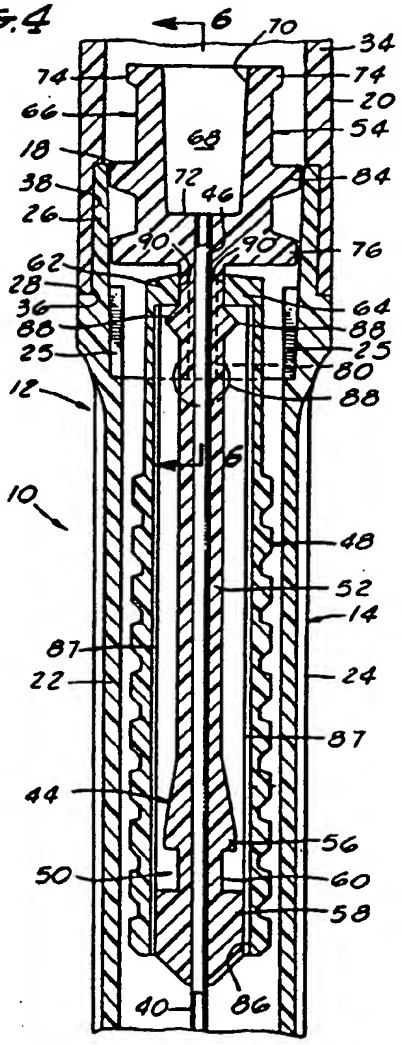

FIG. 5

Kirkus & Murphee
PATENT AGENTS

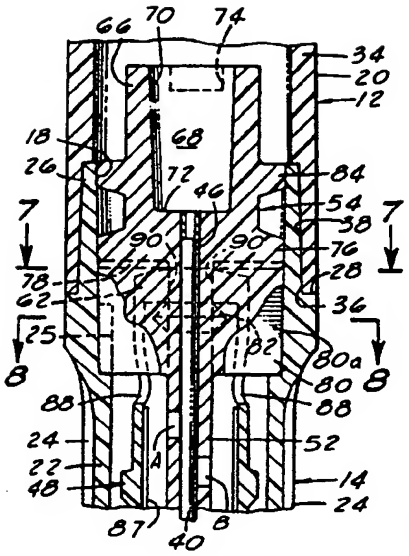

FIG. 6

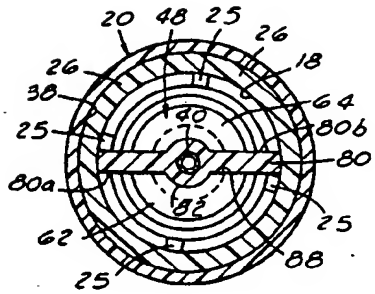

FIG. 7

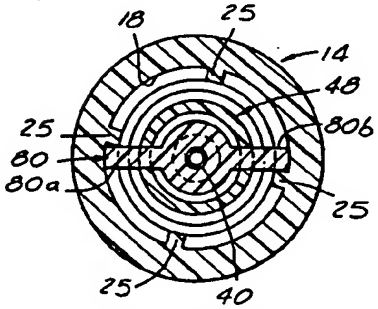

FIG. 8

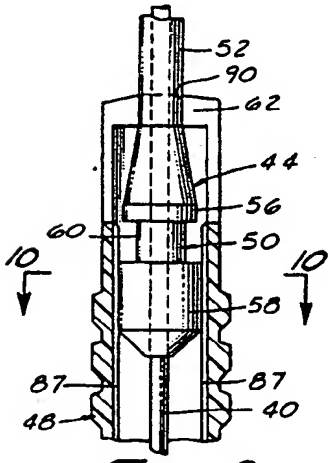

FIG. 9

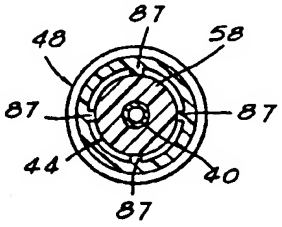

FIG. 10

Watkins & Wrenford
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